DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

December 9, 2004

WARNING LETTER NO. 2005-NOL-06

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. John P. Byrnes, President
Lincare, Inc., and Reliant Pharmacy Services, Inc.
19387 US 19 N
Clearwater, Florida 33764

Dear Mr. Byrnes:

On June 16-18, 2004, the Food and Drug Administration (FDA) inspected your facility located at 1235 Main Street, Southaven, Mississippi. Our investigator documented serious violations of the Federal Food, Drug, and Cosmetic Act (the Act).

As you may be aware, Section 127 of the FDA Modernization Act of 1997 amended the Act by adding Section 503A, which specified conditions under which compounded human drugs could be exempt from certain requirements of the Act. In April 2002, however, the United States Supreme Court struck down the commercial speech restrictions in Section 503A as unconstitutional. Accordingly, all of Section 503A is now invalid.

As a result, the agency now utilizes its longstanding policy of exercising its enforcement discretion regarding certain types of pharmacy compounding. This policy is articulated in Compliance Policy Guide (CPG), Section 460.200, issued on June 7, 2002. The CPG contains factors the agency considers in deciding whether to exercise its enforcement discretion. One factor the agency considers is whether a compounded product is a copy of a commercially available product and, if so, whether there is patient-specific documentation of a medical need for the compounded product.

Based on our inspection, we have determined your operation is akin to that of a drug manufacturer. Relevant findings include the following:

- Your firm's acetylcysteine products are the same strengths (10% and 20%) as those available commercially. The commercial products are available as 10ml and 30ml multidose vials, whereas your firm's products are available as 0.5ml and 5ml single dose vials. We do not view the availability of single-dose vials as meaningful distinction between your products and commercially available products.

- The strengths and sizes of your firm's budesonide products are the same as the commercially available products. We acknowledge the commercially available products are suspensions and your firm's products are solutions, but we do not regard this as a meaningful distinction and your firm's records fail to document patient-specific medical need for the compounded solutions. There is also no documentation physicians were told of and/or approved the use of your compounded products in lieu of the commercially available, FDA-approved products.

- From June 1, 2003, to May 31, 2004, your firm dispensed [redacted] individual doses of [redacted] different compounded products, or [redacted] individual doses per [redacted] percent of these drugs were distributed to patients in [redacted] states. While FDA recognizes some pharmacists extemporaneously compound reasonable quantities of human drugs upon receipt of valid prescriptions for individual patients, your firm produces enormous amounts of what are essentially copies of commercially available drugs. This practice goes well beyond the scope of traditional pharmacy compounding and instead more closely resembles a drug manufacturing operation.

Your firm's operation violates the following Sections of the Act:

Section 505
Your firm's inhalation solutions are "drugs" and "new drugs" within the meaning of Sections 201(g) and (p), respectively, of the Act. Under Section 505 of the Act, they may not be introduced or delivered for introduction into interstate commerce because they lack approved applications.

Section 502(o)
Since your firm manufactures and dispenses drugs in a manner exceeding the bounds of traditional pharmacy compounding, it is not exempt from the registration and drug listing requirements under 21 CFR § 207.10 and Section 510 of the Act. Thus, your drug products are misbranded under Section 502(o) of the Act because they are not listed or manufactured in a duly registered establishment.

In addition to the above violations as a drug manufacturer, you must comply with the Act's Current Good Manufacturing Practice requirements (Section 501(a)(2)(B) of the Act and 21 CFR 211).

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and its regulations. Federal agencies are advised of the issuance of all warning letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to permanently correct these deviations and prevent their recurrence. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of the steps taken to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be complete.

Your reply should be directed to the attention of Kari L. Batey, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217. If you have questions concerning the violations noted, please contact Ms. Batey at (615) 781-5380 extension 112.

Sincerely,

H. Tyler Thornburg
Director, New Orleans District

Enclosures: 21 CFR 207.10 & 211

cc: [redacted]